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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,762	02/09/2001	James R. Connor	P04864US2	6610

27407 7590 07/23/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,762

Applicant(s)

CONNOR ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17,26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 12) filed on May 14, 2003 has been entered and considered.
2. Claim 21 is cancelled. Claims 1, 3-17, 26 and 27 are pending.

Response to arguments

3. Applicants' response to the office action (Paper No. 17) is fully considered and found persuasive in part.
4. With reference to the rejection made in the previous office action under 35 USC 102(b) applicant's amendment and arguments are fully considered and the rejection is withdrawn in view of the amendment (Paper No. 12).

5. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 1, 3-17, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (USPN. 6,203,984) in view of Li et al. (USPN. 6,3999,334).

Hu et al. teach a method for amplifying cDNA comprising (i) obtaining an mRNA (see column 12, lines 43-50); (ii) reverse transcribing the mRNAs into cDNA with reverse transcriptase to form cDNA-mRNA complex (see column 12, lines 51-67, column 13, lines 1-7, column 1, lines 57-67, column 2, lines 1-2, column 10, lines 29-4); (iii) degrading the mRNA from the cDNA-mRNA complex to form a linear cDNA (see column 13, lines 9-25, column 1, lines 67, column 2, line 1, column 10, lines 47-58); (iv) ligating the ends of said linear cDNA to form a circular cDNA (see column 2, lines 1-4, column 13, lines 27-41, column 10, lines 58-67); (v) introducing first and second specific primers to said circular cDNA and amplifying the cDNA using primer extension amplification (see column 2, lines 4-26, column 11, lines 1-28). Further,

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Hu et al. teach that the method comprises primer extension by PCR (see column 10, lines 13-18); Taq DNA polymerase (see column 10, lines 13-18); harvesting said amplified cDNA into a vector (see column 10, lines 18-28); first and second primers were designed to hybridize to from about at least 12 nucleotides to the mRNA (see column 9, lines 57-67, column 10, line 1); one of the primers comprise at least same 3' end which is towards the 3' end of the said mRNA (see column 9, lines 57-67, column 10, line 1). Although Hu et al. used reverse transcriptase, Hu et al. did not specifically teach a reverse transcriptase without RNase H activity.

Li et al. teach a method for amplifying cDNA wherein Li et al. teach that the method comprises use of reverse transcriptase without RNase H activity (see column 11, lines 17-39).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the method of amplifying cDNA as taught by Hu et al. with the reverse transcriptase RNase H⁻ as taught by Li et al. to achieve expected advantage of developing an efficient amplification method because Li et al. suggests that "the invention provides removal of contaminating or background nucleic acid molecules from the normalized library, and such removal or elimination of contaminating nucleic acids might be performed prior to or after normalization" (see column 15, lines 9-26). An ordinary practitioner would have been motivated to combine the teachings of Hu et al. with the method of Li et al. to achieve a sensitive method of the amplifying cDNA by incorporating the reverse transcriptase RNase H⁻ because this limitation would improve the elimination or reduce background contamination.

Response to arguments:

Applicant's arguments with reference to the above rejection are fully considered. With

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reference to the obligation under 37 CFR 1.56, applicant's arguments are fully considered and found persuasive. The obligation made in the previous office action was an error and it is withdrawn herein.

With reference to the above rejection, Applicant's arguments are fully considered and found not persuasive. Applicant argues that there is no teaching or suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, specific motivation is provided by the teachings of Hu et al. and Li et al. to improve sensitivity of the assay. An ordinary practitioner would have been motivated to combine the teachings of Hu et al. with the method of Li et al. to achieve a sensitive method of the amplifying cDNA by incorporating the reverse transcriptase RNase H⁻ because this limitation would improve the elimination or reduce background contamination.

Applicant argues that it is more difficult to obtain full length double stranded cDNA than to obtain full length first single strand DNA. The issue here is amplification of cDNA irrespective of a double or single stranded cDNA. The instant claims do not recite this limitation and hence the argument is irrelevant. Applicant further argues that Hu et al. does not teach the use of two specific PCR primers as shown in Fig. 1 of the specification. However, as stated in MPEP 2145, "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims". In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057

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(Fed. Cir. 1993), the instant independent claims 28 and 35 do not recite this limitation and specification is not be read into the claims.

Applicant also argues that the second primer is added in a later step, that is after ligation. This argument is found not persuasive because the instant claims are in open "comprising" format and hence any additional step or element can be included. Further, HU et al. clearly teaches cDNA can also be amplified using polymerase chain reaction (see column 7, lines 17-31) which clearly indicates single cDNA is amplified using standard PCR method wherein forward and reverse primers are used to amplify cDNA. Finally Applicant argue that Hu et al. fail to teach specific PCR primers as claimed in the instant dependent claims 26 and 27, which is found not persuasive because as stated above obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

Therefore, the rejection is maintained herein.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
July 18, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER